United States Environmental Protection Agency
Washington, D.C. 20460
DATA CALL-IN RESPONSE

OMB Approval 2070-0174
EPA FORM 6300-4

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
HELM AGRO US, INC. 1087 HEARTSEASE DRIVE WEST CHESTER, PA 19382	N/A - Tebuconazole Chemical # and Name: 128997 Tebuconazole	14-Sep-2017 GENERIC ID # GDCI-128997-1598

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data Requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirement on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirement on the attached form entitled "Requirements Status and Registrant's Response."
74530-67			X	N/A	N/A

8. Certification: I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative: Rat Mgr, Agent

9. Date: 12/18/2017

10. Name of Company: Helm Agro US, Inc.

11. Phone Number: 610 793 3222

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0174
EPA FORM 6300-3

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

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HELM AGRO US, INC. 1087 HEARTSEASE DRIVE WEST CHESTER, PA 19382	N/A - Tebuconazole Chemical # and Name: 128997 Tebuconazole	14-Sep-2017 GENERIC ID # GDCI-128997-1598

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
	Applicator Exposure Data Requirements (Conventional Chemical)									Option
875.1200	Dermal exposure--Indoor	**(15, 19, 41)**	Y				A,C,Q,X,BB	TEP	12	2
875.1400	Inhalation exposure--indoor	**(15, 19, 41)**	Y				A,C,Q,X,BB	TEP	12	2
875.1700	Product Use Information	**(15, 22)**	N				A,C,Q,X,BB	TEP	12	2
	Nontarget Plant Protection Data Requirements (Conventional Chemical)									
850.4100	Seedling Emergence and Seedling Growth	**(6, 14)**	N				A,C,Q,X,BB	TEP	12	2
850.4150	Vegetative Vigor	**(7, 14)**	N				A,C,Q,X,BB	TEP	12	2
	Post-Application Exposure Data Requirements (Conventional Chemical)									
875.2100	Foliar dislodgeable residue dissipation	**(14, 28)**	N				A,C,Q,X,BB	TEP	12	2
875.2300	Indoor surface residue dissipation	**(15, 17, 39, 41)**	Y				A,C,Q,X,BB	TEP	12	2

10. Certification: I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative: [signature], Agent

11. Date: 12/18/2017

12. Name of Company: Helm Agro US, Inc.

13. Phone Number: 610-793-3222

United States Environmental Protection Agency
Washington, D.C. 20460
REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0174
EPA FORM 6300-3

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HELM AGRO US, INC. 1087 HEARTSEASE DRIVE WEST CHESTER, PA 19382	N/A - Tebuconazole Chemical # and Name: 128997 Tebuconazole	14-Sep-2017 GENERIC ID # GDCI-128997-1598

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
	Terrestrial and Aquatic Nontarget Organisms Data Requirements (Conventional Chemical)									Option
850.2100	Avian acute oral toxicity test	**(14, 23)**	N				A,C,Q,X,BB	TGAI	12	2
850.3020	Honey bee acute contact toxicity	**(8, 14, 21)**	N				A,C,Q,X,BB	TGAI	12	2
850.3030	Honey bee toxicity of residues on foliage	**(2, 9, 14, 41)**	Y				A,C,Q,X,BB	TEP	12	2
850.3040	Field testing for pollinators	**(1, 3, 14, 20, 41)**	Y				A,C,Q,X,BB	TEP	24	2
835.1110	Activated sludge sorption isotherm	**(15, 34)**	N				A,C,Q,X,BB	TGAI	12	2
835.3110	Ready biodegradability	**(15, 33)**	N				A,C,Q,X,BB	TGAI	12	2
835.3220	Porous pot test	**(15, 32)**	N				A,C,Q,X,BB	TGAI	12	2
835.3240	Simulation Test-Aerobic Sewage Treatment-Activated Sludge	**(15, 31)**	N				A,C,Q,X,BB	TGAI	12	2

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4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
										Option
835.3280	Simulation Tests to Assess the Biodegradability of Chemicals	**(15, 30)**	N				A,C,Q,X,BB	TGAI	12	2
850.3300	Modified Activated Sludge, Respiration Inhibition Test	**(15, 18, 24, 29)**	N				A,C,Q,X,BB	TGAI	12	2
850.4500	Algal Toxicity	**(16, 25, 38)**	N				A,C,Q,X,BB	TGAI, TEP	12	2
850.4550	Cyanobacteria (Anabaena flos-aquae) Toxicity	**(16, 25)**	N				A,C,Q,X,BB	TGAI, TEP	12	2
850.6100	Environmental Chemistry Methods and Associated Independent Laboratory Validation	**(14, 35)**	N				A,C,Q,X,BB	TGAI	12	2
SS-1196	Whole Sediment: Chronic toxicity to saltwater invertebrates	**(16, 37, 41)**	Y				A,C,Q,X,BB	TGAI	24	2
SS-1197	Whole Sediment: Chronic toxicity to freshwater invertebrates	**(16, 36, 41)**	Y				A,C,Q,X,BB	TGAI	24	2
SS-1311	Honey bee adult acute oral toxicity	**(10, 14)**	N				A,C,Q,X,BB	TGAI	12	2
SS-1312	Honey bee larvae acute oral toxicity	**(13, 14)**	N				A,C,Q,X,BB	TGAI	12	2

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4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
										Option
SS-1313	Honey bee adult chronic oral toxicity	**(11, 14, 41)**	Y				A,C,Q,X,BB	TGAI	12	2
SS-1314	Honey bee larvae chronic oral toxicity	**(12, 14, 41)**	Y				A,C,Q,X,BB	TGAI	12	2
SS-1315	Semi-field testing for pollinators	**(5, 14, 26, 27, 41)**	Y				A,C,Q,X,BB	TGAI, TEP	24	2
SS-1316	Field trial of residues in pollen and nectar	**(4, 14, 40)**	Y				A,C,Q,X,BB	TEP	24	2

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FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: N/A - Tebuconazole
DCI Number: GDCI-128997-1598

Key: [Degr] = Degradate; [d-EP] = diluted End-use product; [EP] = End-use product; [MET] = Plant metabolite; [MP] = Manufacturing-use product; [PAI] = Pure Active Ingredient; [PAIRA] = Pure active ingredient radio-labelled; [RAMET] = Radio-labeled plant metabolite; [ROC] = Residue of Concern; [TEP] = Typical end-use product; [TGAI] = Technical grade of the active ingredient; [TW] = Treated wood

Use Categories Key:

A - Terrestrial food crop

C - Terrestrial nonfood crop

Q - Residential outdoor use

X - Materials preservatives

BB - Wood preservatives

Footnotes: The following footnotes are referenced in column two (5. Study Title) of the Requirements Status and Registrant's Response form. These footnotes apply in addition to any test notes included in 40 CFR Part 158 with respect to the particular data requirement.

1	USEPA. 2012c. "Field Testing for Pollinators." Ecological Effects Test Guidelines OCSPP 850.3040. EPA 712-C-017.
2	USEPA. 2012b. "Honey Bee Toxicity of Residues on Foliage." Ecological Effects Test Guidelines OCSPP 850.3030. EPA 712-C-018.
3	Tier 3 study. The need for a field test for pollinators will be determined based on the results of lower-tiered tests and/or other lines of data and the need for a refined pollinator risk assessment.
4	Tier 2 study. The need for this study will be determined based on the results of lower-tiered studies and/or other lines of data and the need for a refined pollinator risk assessment.
5	Tier 2 study. The need for a semi-field test for pollinators (i.e., either a field-feeding test or a tunnel test) will be determined based on the results of lower-tiered tests and/or other lines of evidence, and the need for a refined pollinator risk assessment.
6	Tier 2 data on monocots are required.
7	Tier 2 data on dicots and monocots are required.
8	Tier 1 study. USEPA. 2012a. "Honey Bee Acute Contact Toxicity" Ecological Effects Test Guidelines OCSPP 850.3020. EPA 712-C-019
9	Tier 1 study. Guideline 850.3030 data are required when the product formulation contains one or more active ingredient(s) having an acute LD50 of < 11 micrograms per bee as determined in the honey bee acute contact study and the use pattern(s) indicate(s) that honey bees may be exposed to the pesticide.
10	Tier 1 study. See the OECD 213: OECD Guidelines for the Testing of Chemicals. Honeybees, Acute Oral Toxicity Test. 213. http://www.oecd-ilibrary.org/environment/test-no-213-honeybees-acute-oral-toxicity-test_9789264070165-en
11	Tier 1 study. OECD has not yet finalized test guidelines for chronic studies, and efforts are underway to develop standardized guidelines for assessing the effects from chronic exposure to adult and larvae in the laboratory. Discussion of the study design elements for the 10-day adult toxicity test can be found in Appendix O of the European Food Safety Authority (EFSA) guidance document: EFSA. 2013. Guidance on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees). EFSA Journal 2013;11(7):3295, 266 pp. doi:10.2903/j.efsa.2013.3295. Available online at: https://www.efsa.europa.eu/en/efsajournal/pub/3295
12	Tier 1 study. OECD has not yet finalized test guidelines for chronic studies with honey bee larvae. OECD Draft Guidance Document Honey Bee (Apis mellifera) Larval Toxicity Test, Repeated Exposure. https://www.oecd.org/env/ehs/testing/Honeybee%20larval%20rep%20expo_REV%20following%20April%202015%20expert%20meeting_Draft%2020%20July%202015.pdf
13	Tier 1 study. OECD Test Guideline 237 may be used to develop a protocol for this study (OECD. 2013 Guidelines for Testing Chemicals. Honey bee (Apis mellifera) larval toxicity test, single exposure.) See: http://www.oecd-ilibrary.org/environment/test-no-237-honey-bee-apis-mellifera-larval-toxicity-test-single-exposure_9789264203723-en
14	This study is required only in support of conventional uses.

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FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

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15 This study is required only in support of antimicrobial uses.

16 This study is required in support of both antimicrobial and conventional uses.

17 The wipe study is based on the need to assess dermal and incidental oral exposures to children (age 1-2) playing on pressure treated decks and play sets.

18 The results of the Activated Sludge, Respiration Inhibition Test (ASRI), GLN 850.3300, will determine which of the four biodegradation tests are required.

If the ASRI test results in an EC50 of less than or equal to 20 mg/L, then either the (i) Simulation tests to assess the biodegradability of chemicals discharged in wastewater, GLN 835.3280, (ii) the Simulation Test-Aerobic Sewage Treatment: A. Activated Sludge Units, GLN 835.3240, or (iii) the Porous Pot Test, GLN 835.3220 is required.

If the ASRI test results in an EC50 greater than 20 mg/L, then the registrant is required to conduct either the (i) Ready Biodegradability, GLN 835.3110, (ii) Simulation tests to assess the biodegradability of chemicals discharged in wastewater, (iii) the Simulation Test-Aerobic Sewage Treatment: A. Activated Sludge Units, or (iv) the Porous Pot Test.

If the Ready Biodegradability Study is conducted and passes, then no further testing is required. If, however, the pesticide fails the Ready Biodegradability study, then the (i) Simulation tests to assess the biodegradability of chemicals discharged in wastewater, (ii) the Simulation Test-Aerobic Sewage Treatment: A. Activated Sludge Units, or (iii) the Porous Pot Test is required.

19 The following data/scenarios are needed: pressure treatment, liquid pour, sapstain, brush/roller, and airless sprayer.

20 See information and guidance identified in the EPA documents, (i) USEPA. 2012. White Paper in Support of the Proposed Risk Assessment Process for Bees. Submitted to the FIFRA Scientific Advisory Panel for Review and Comment September 11-14, 2012. Office of Chemical Safety and Pollution Prevention Office of Pesticide Programs Environmental Fate and Effects Division, Environmental Protection Agency, Washington DC; Environmental Assessment Directorate, Pest Management Regulatory Agency, Health Canada, Ottawa, CN; California Department of Pesticide Regulation; (ii) 2014 Guidance for Assessing Pesticide Risks to Bees. Office of Pesticide Programs United States Environmental Protection Agency, Health Canada Pest Management Regulatory Agency, California Department of Pesticide Regulation. June 19, 2014. https://www.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf

21 See also OECD 214: OECD.1998b. OECD Guidelines for the Testing of Chemicals. Test Number 214, Acute Contact Toxicity Test. http://www.oecd-ilibrary.org/environment/test-no-214-honeybees-acute-contact-toxicity-test_9789264070189-en

22 Product use data is needed to clarify uses (particularly the use of plastics in toys), application rates and wood retentions, and application equipment.

23 Only passerine species toxicity data are required.

24 OECD Test Guideline 209 can also be used as guidance for this study, available online at http://www.oecd-ilibrary.org/content/book/9789264070080-en

25 In a Federal Register Notice dated June 27, 2012, EPA split the Public Draft OPPTS 850.5400 test guideline into two test guidelines: OCSPP 850.4500 and OCSPP 850.4550. See "Final Test Guidelines; OCSPP 850 Series; Notice of Availability" 77 FR 38282, June 27, 2012. https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0154-0028.

26 Formal guidelines for semi-field tests do not yet exist; however, information that can help guide the development of a semi-field tunnel test protocol can be found at OECD 75, see: OECD. 2007. Series on Testing and Assessment Number 75. Guidance document on the honey bee (Apis mellifera L.) brood test under semi-field conditions. Environmental Directorate Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology. ENV/JM/MONO(2007)22. 31-Aug-2007. http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2007)22&doclanguage=en.

27 For field-feeding studies see: Oomen et al. 1992: Oomen, P. A. A. DeRuijter and J. Van der Steen. 1992. Method for honey bee brood feeding tests with insect growth-regulating insecticides. Bul OEPP/EPPO Bulletin 22: 613-616.

28 Foliar dislodgeable and turf transferrable residue dissipation data are required for post-application worker or residential exposure.

29 EPA published draft guidance under guideline 850.6800 and has since published final guidance for this study under guideline 850.3300: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0154-0021.

30 EPA has a published final guideline for this study: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0152-0036. The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test.

31 EPA has a published final guideline for this study: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0152-0034. The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test.

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32 EPA has a published final guideline for this study: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0152-0024. The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test.

33 EPA has a published final guideline for this study: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0152-0017. The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test.

34 EPA has a published final guideline for this study: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0152-0003.

35 ECM/ILV needed for soil and water.

36 Chronic sediment toxicity data required on two freshwater species (an amphipod and a midge) in support of conventional uses. Only the freshwater amphipod data are required in support of antimicrobial uses.

37 Chronic sediment toxicity data required on one species of estuarine/marine amphipod.

38 Algal toxicity data required on two species of non-vascular plants (freshwater and marine diatoms).

39 A waiver may be requested for all applications if a residue screening level default at 100% of the application rate does not trigger risk concerns.

40 A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation. The following elements could be considered when developing study protocol(s) for the monitoring of residues in pollen/nectar.
1) Consideration of the range of application methods and environmental conditions (e.g., soil and hydric regimes) that the target crop(s) may be under.
2) Consideration of the attractiveness of the selected crop to pollinators.
3) Consideration of a collection schedule sufficient to allow for an understanding of the character of residues, in the pollen/nectar and/or plant tissues, over time.
4) Consideration of data sufficient to determine whether residues of the active ingredient and/or degradation product(s) accumulates in soil and is/are bioavailable for plant to uptake in a following planting, and therefore result in potential exposure to pollinators.
5) Consideration of the market proportion of the selected target crop(s).

41 A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.